

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 2003012-WO	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/DK2004/000157	International filing date (day/month/year) 12.03.2004	Priority date (day/month/year) 17.03.2003
International Patent Classification (IPC) or national classification and IPC A61F5/445, A61F5/441, A61F5/448		
Applicant COLOPLAST AS ET AL.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 4 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 13.05.2005	Date of completion of this report 07.07.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Germano, A Telephone No. +31 70 340-4202 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/DK2004/000157

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-14 received on 12.05.2005 with letter of 12.05.2005

Drawings, Sheets

1/4-4/4 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☒ the claims, Nos. 15
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
 - ☒ claims Nos. 14
because:
 - ☒ the said international application, or the said claims Nos. 14 relate to the following subject matter which does not require an international preliminary examination (specify):
see separate sheet
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☐ no international search report has been established for the said claims Nos.
 - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
 - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
 - ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/DK2004/000157

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-13
	No: Claims	
Inventive step (IS)	Yes: Claims	1-13
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-13
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The method described in claim 14 comprises within its scope methods of treatment of the living body by surgery or therapy. According to Art. 34(4)(a)(I), 34(4)(b) and Rule 67(1)(iv), the IPEA is not required to carry out a substantive examination for such matter.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Document DE-A-19 519 069 reflects the closest prior art. This document (see col. 2, line 53, to col. 3, line 40 and fig. 1, the reference signs applying to said document while the wording is that of claim 1): discloses:
 - 2.1 "an ostomy appliance comprising a base plate (3), said base plate (3) having a first hole for receiving a stoma, ureter or catheter and an adhesive wafer (1) having a first surface to be attached to the wearer's abdomen, back or chest; a receiving member or bag (4) releasably attached to the base plate (3), said bag (4) having a second hole for receiving wastes exiting the stoma, ureter or catheter, and a disposable inner bag liner (8) forming a second bag inside the receiving member or bag (4) and being releasably attachable to the base plate (3) in a first coupling area by first coupling means (7, see fig. 1), said disposable inner bag liner (8) having a third hole for receiving wastes exiting the stoma, ureter or catheter and the receiving member or bag (4) being releasably attachable to the base plate (3) by second coupling means (6), wherein the first coupling means is in the form of a flange (7) projecting from the rim of the third hole (9) and having a surface for releasable sealing against a second surface of the base plate (3) facing away from the user"
 - 2.2 The subject-matter of claim 1 differs from the disclosure of this document in that it specifies that:

- a) the flange forming the first coupling means is adhesive, and
- b) the inner bag liner is provided with folding lines for compacting the bag lengthwise. In view of these differences the subject matter of claim 1 is new and meets the requirements of Art. 33(2) PCT.

2.3 Feature a) does not go beyond the application of well known measures in an obvious way. For the skilled man it would be evident that the flange of the bag and the base plate can be releasably connected also by means of adhesive. The feature, moreover, is disclosed for the same purpose in the prior art, see for example US-A-5 591 144, col. 2, lines 1-5 and col. 4, line 38-42 and US-A-5 785 695, see col. 2, lines 1-5.

Feature b) is not disclosed in the available prior art documents.

The scope of the feature is avoid the walls of the inner bag to block unintentionally the output from the stoma of the patient.

None of the available prior art documents suggests this feature for the above mentioned scope.

In view of that the subject-matter of claim 1 involves an inventive step and meets the requirements of Art. 33(3) PCT.

- 3. Independent claims 7 and 12 repeat, using a slight different wording, some of the features of claim 1 and differ from the disclosure of said DE-A-19 519 069 by the same features a) and b) cited at point 2.2 above.

In view of that claims 7 and 12 meet the requirements of novelty of Art. 33(2) PCT and the requirements of an inventive step of Art. 33(3) PCT, see point 2.2 above.

- 4. The devices described in claims 1, 7 and 12 are industrially manufacturable. Therefore the claims meet the requirements of Art. 33(4) PCT
- 5. Claims 2 to 6, 8 to 11 and 13, dependent from claims 1, 7 and 12 respectively, are directed to specific aspects of the devices claimed in the claims from which they depend and therefore meet the requirements of Art. 33(2), (3) and (4) PCT for the

same reasons explained above.

Re Item VII

Certain defects in the international application

6. According to Rule 5.1(a)(ii) PCT, the relevant background art disclosed in DE-A-19 519 069 should have been mentioned in the description and this document identified therein.
7. The description should have been brought into conformity with the claims as required by Rule 5.1(a)(iii) PCT.
8. The independent claims should have been cast in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would have been appropriate, with those features known in combination from the prior art (see point 2.1 above) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features (see point 2.2 above) being included in the characterising part (Rule 6.3(b)(ii) PCT).
9. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

10. Independent claims 7 and 12 merely repeat features which are already described in independent claim 1.
Moreover, the dependent claims also repeat the same features.
In view of that the claims do not comply with the requirements of clarity and conciseness of Art. 6 PCT.

Amended Claims

1. An ostomy appliance comprising a base plate, said base plate having a first hole for receiving a stoma, ureter, or catheter and an adhesive wafer having a first surface to be attached to the wearer's abdomen, back, or chest; a receiving member or bag releasably attached to the base plate, said bag having a second hole for receiving wastes exiting the stoma, ureter or catheter; and a disposable inner bag liner forming a second bag inside the receiving member and being releasably attachable to the base plate in a first coupling area by first coupling means, said disposable inner bag liner having a third hole for receiving wastes exiting the stoma, ureter or catheter and the receiving member being releasably attachable to the base plate by second coupling means wherein the first coupling means is in the form of an adhesive flange projecting from the rim of the third hole and having a surface for releasable sealing against a second surface of the base plate facing away from the user and wherein the inner bag liner is provided with folding lines for compacting the bag lengthwise.
2. An ostomy appliance as claimed in claim 1 wherein the second coupling means is in the form of an adhesive flange projecting from the rim of the second hole and having a surface for adhesive sealing against the second surface of the base plate.
3. An ostomy appliance as claimed in claim 2 wherein the outer diameter of the first coupling means is greater than the inner diameter of the second coupling means.
4. An ostomy appliance as claimed in any of claims 2 or 3 wherein the peel strength of the adhesive sealing of the first coupling means is greater than the peel strength of the second couplings means.
5. An ostomy appliance as claimed in claim 1 wherein the second coupling means is in the form of one or more coupling rings and wherein the outer

diameter of the first coupling means is smaller than the inner diameter of the second coupling means.

- 5 6. An ostomy appliance as claimed in any of claims 1-6 wherein the inner bag liner is provided with a membrane allowing intestinal gas to escape but is impermeable to liquids.

- 10 7. An ostomy appliance comprising an adhesive wafer, said adhesive wafer having a first hole for receiving a stoma, ureter, or catheter, said adhesive wafer having a first surface to be attached to the wearer's abdomen, back, or chest and a receiving member or bag attached to the adhesive wafer, said bag having a second hole for receiving wastes exiting the stoma, ureter or catheter; and a disposable inner bag liner forming a second bag inside the receiving member and being releasably attachable to the adhesive wafer by first coupling means, said
15 disposable inner bag liner having a third hole for receiving wastes exiting the stoma, ureter or catheter wherein the first coupling means is in the form of an adhesive flange projecting from the rim of the third hole and having a surface for releasable sealing against a first surface of the adhesive wafer and wherein the inner bag liner is provided with folding lines for compacting the bag lengthwise.

- 20 8. An ostomy appliance as claimed in any of claims 1-7 wherein the inner bag liner is compacted lengthwise to form a disc-like structure having an outer diameter less than the inner diameter of the first coupling means.

- 25 9. An ostomy appliance as claimed in any of the claims 1-8 wherein the folding lines form a bellows.

10. An ostomy appliance as claimed in any of the claims 1-8 wherein the folding lines form a telescopic bellows.

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11. An ostomy appliance as claimed in any of claims 1-10 wherein the closed end of the compacted inner bag liner is provided with a cover.

12. A disposable inner bag liner for receiving effluents or waste products of the body and for use together with an ostomy appliance comprising an adhesive wafer to be attached to the wearer's abdomen, back, or chest and a receiving member or bag having a hole for receiving wastes exiting the stoma, ureter or catheter, said disposable inner bag liner having a hole for receiving wastes exiting the stoma, ureter or catheter and being capable of forming a bag inside the receiving member for being releasably attachable to the adhesive wafer in a first coupling area by first coupling means wherein the first coupling means is in the form of an adhesive flange projecting from the rim of the hole and having a surface for releasable sealing against a surface of the adhesive wafer wherein the inner bag liner is provided with folding lines for compacting the bag lengthwise.
13. A disposable inner bag liner as claimed in claim 12 wherein the inner bag liner is provided with a membrane allowing intestinal gas to escape from the inner bag liner but is impermeable to liquids.
14. A method of applying an ostomate an ostomy appliance comprising a base plate, said base plate having a first hole for receiving a stoma, ureter, or catheter and an adhesive wafer having a first surface to be attached to the wearer's abdomen, back, or chest; a receiving member or bag releasably attachable to the base plate, said receiving member having a second hole for receiving wastes exiting the stoma, ureter or catheter; and a disposable inner bag liner forming a second bag inside the receiving member and being releasably attachable to the base plate, said disposable inner bag liner having a third hole for receiving wastes exiting the stoma, ureter or catheter, said inner bag liner being compacted lengthwise to form a disc-like structure, and said inner bag liner being attachable releasably to the base plate in a first coupling area by first coupling means and the receiving member being attachable releasably to the base plate by second coupling means wherein the first coupling means is in the form of an adhesive flange projecting from the rim of the third hole and having a surface for adhesive

- sealing against a second surface of the base plate facing away from the user, said method comprising locating the stoma and applying the base plate, locating the inner bag liner and applying and sealing the same to the first coupling area, removing release liner covering first coupling means if present, and attaching the
- 5 receiving member to the base plate.